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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,597	03/25/2004	Michael Kenneth Cerreta	9/266	1495

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EXAMINER

KOSAR, ANDREW D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/809,597	CERRETA ET AL.	
	Examiner	Art Unit	
	Andrew D Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-9 and 14-19 is/are allowed.
- 6) ☒ Claim(s) 12,13,22 and 24-26 is/are rejected.
- 7) ☒ Claim(s) 10,11,20,21 and 23 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>20041027</u> . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/22/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-26 are pending in the instant application. Claims 10-13, 15, and 20-23 are objected to, Claims 12, 13, 22, and 24-26 are rejected, and Claims 1-11 and 14-21 have been found to be free of the prior art.

A telephone call to Applicant's Attorney was placed on October 27, 2004 regarding the instant claims. Applicant's Attorney requested that proposed amendments to the claims which would distinguish the instant claims over the prior art be presented by the Examiner with this Office Action.

Claim Objections

Claims 10-13, 15, and 20-22 are objected to because of the following informalities:

Claims 10-13 and 20-22 are drawn to methods of making crystalline forms of Compound (I) and product-by-process claims. While it is assumed that the product is formed at the conclusion of the last step, the instant claims fail to indicate as such.

Applicant is suggested to amend the claims to include either, "whereby the crystalline phase of Compound (I) is formed" or "to form the crystalline phase of compound (I)" at the end of the claimed steps.

A typographical error is noted in Claim 15, "characteristic at least peaks", which should read, "characteristic peaks at least".

Appropriate correction is required.

Claim 23 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can only depend from previous claims in the alternative. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Art Unit: 1654

Applicant is advised that incorporation of all of the limitations of claims 14 and 22 into the claim will overcome this objection.

Proposed amendments to the claims are presented at the end of this Office Action.

Claim Rejections - 35 USC § 102 and 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12, 13, 22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 00/59929 A1¹ ('929).

The instant claims are drawn to a crystalline phase of Compound (I) and a pharmaceutical composition of Compound (I). Claims 12, 13, and 22 are product-by-process claims, and have been treated as reading upon the compound. Because the claims do not recite characteristic XRPD peak positions, it is the Examiner's position

¹ PTO-1449, 9/22/04.

Art Unit: 1654

that the teaching of the compound in the prior art reads upon the instantly claimed phase.

Applicant states in the instant specification that Compound (I) is compound #822 in '929 [and is found in example 34c, page 93 of '929] (see Instant specification, page 1).

Compound (I) is taught as Compound #822 in '929 (page 93, Example 34c) and in Claim 52. While '929 is silent to the morphology of the compound and the percentage of a specific phase, it is the Examiner's position, absent evidence to the contrary, that the having a crystalline phase is an inherent physical trait of the compound, and that the method of Example 34 (page 88+) would result in a crystalline phase meeting the limitations of the instant claims. Therefore, the teachings of '929 appear to anticipate the instantly claimed inventions.

In the alternative, even if the claimed product is not identical to the referenced product with regards to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced product is likely to inherently possess the same characteristics of the claimed product, particularly in view of the similar characteristics which they have been shown to share (such as chemical structure, biological activity, and use in treating HCV). Thus, the claimed product would have been obvious to those of ordinary skill in the art within the meaning of 35 USC 103.

Art Unit: 1654

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to contrary.

Claims 12, 13, 22, 24, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent 6,608,027 B1² ('027).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The instant claims are presented *supra*.

Claims 108 and 115 of '027 teach compound #822, as defined *supra*, and a pharmaceutical composition of #822, respectively.

While '027 is silent to the morphology of the compound and purity, it is the Examiner's position, absent evidence to the contrary, that the having a crystalline phase is an inherent physical trait of the compound, and that the method of Example 34 (column 92+) would result in a crystalline phase which meets the limitations of the instant claims. As such, it appears that the teachings of '027 anticipate the instantly claimed inventions.

² PTO-1449, 9/22/04.

Art Unit: 1654

In the alternative, even if the claimed product is not identical to the referenced product with regards to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced product is likely to inherently possess the same characteristics of the claimed product, particularly in view of the similar characteristics which they have been shown to share (such as chemical structure, biological activity, and use in treating HCV). Thus, the claimed product would have been obvious to those of ordinary skill in the art within the meaning of 35 USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to contrary.

Claim Rejections - 35 USC § 103

The statute for 35 USC § 103 is *supra*.

Claims 12, 13, 22, and 24-26 rejected under 35 U.S.C. 103(a) as being unpatentable over '929 as applied to claims 12, 13, 22, and 24 above.

The instant claims are further drawn to a method of treating HCV with the compound of formula (I).

The teachings of '929 are *supra*. '929 further teaches that the compounds of the invention are used for treating HCV (page 1), that pharmaceutical compositions are made of the instantly claimed compounds (page 6) and that they are administered to a mammal in a anti-hepatitis C virally effective amount (page 6).

Because #822 is a preferred embodiment, as being a specifically claimed compound, and because the specification teaches that the compounds are formed into pharmaceutical compositions and are used in methods for treating HCV, one would have been motivated and it would have been obvious to one of ordinary skill in the art at the time of the invention to make a pharmaceutical composition of #822 and administer it to treat HCV. One would have a reasonable expectation for success in making a pharmaceutical composition and treating HCV with compound #822, as '929 teaches that the compounds are for treating HCV, and are formulated in pharmaceutical compositions.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 12, 13, 22, and 24-26 rejected under 35 U.S.C. 103(a) as being unpatentable over '027 as applied to claims 12, 13, 22, 24, and 25 above.

The teachings of '027 are *supra*. '027 further teaches that the compounds of the invention are used for treating HCV in a anti-hepatitis C virally effective amount (claim 143).

Because #822 and pharmaceutical compositions of #822 are preferred embodiments, as being a specifically claimed, and because the compounds of the genus of compound (I) are used in methods for treating HCV, one would have been

Art Unit: 1654

motivated and it would have been obvious to one of ordinary skill in the art at the time of the invention to administer #822 to treat HCV. One would have a reasonable expectation for success in treating HCV with compound #822, as '027 teaches that the compounds of the genus are used for treating HCV, and because #822 is a claimed embodiment of the genus.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 12, 13, 22, and 24-26 are rejected. Claims 10-13 and 20-23 are objected to.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12, 13, 22, and 24-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 108, 115, and

Art Unit: 1654

143 of U.S. Patent No. 6,608,027. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a crystalline phase of compound (I), a pharmaceutical composition, and a method of use and the prior art teaches compound (I) as #822, a pharmaceutical composition, and the method of use of the genus, wherein #822 is a species. The teachings of '027 are presented *supra*. The prior art is silent to the method of use of the particular species and the morphology of the compound; however absent evidence to the contrary, the prior art method disclosed for making compound (I) would result in a crystalline phase, and that being a species of the genus of compounds used in the method, the instantly claimed compound would be used in the method.

Because #822 and pharmaceutical compositions of #822 are preferred embodiments, as being a specifically claimed, and because the compounds of the genus of compound (I) are used in methods for treating HCV, one would have been motivated and it would have been obvious to one of ordinary skill in the art at the time of the invention to administer #822 to treat HCV. One would have a reasonable expectation for success in treating HCV with compound #822, as '027 teaches that the compounds of the genus are used for treating HCV, and because #822 is a claimed embodiment of the genus. Even if the claimed product is not identical to the referenced product with regards to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced product is likely to inherently possess the same characteristics of the claimed product, particularly in view of the similar characteristics which they have been

Art Unit: 1654

shown to share (such as chemical structure, biological activity, and use in treating HCV). Thus, the claimed product would have been obvious to those of ordinary skill in the art.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Allowable Subject Matter

Claims 1-9 and 14-19 are allowed.

Claims 10, 11, 20, and 21 are allowable but are objected to as indicated *supra*.

The following is a statement of reasons for the indication of allowable subject matter: The prior art does not anticipate or render obvious crystalline phases of compound (I) with the instantly claimed diffraction patterns.

Proposed Amendments to the Claims

At Applicant's request, the Examiner is providing proposed amendments to the claims which will distinguish over the prior art and clarify the instant claims.

Claim 23 may be amended to recite:

"A compound comprising a crystalline phase of Compound (I) according to claims 1, 12, 13, 14, or 22, or a mixture thereof."

This proposed amendment will rectify the improper multiple dependency and distinguish over the prior art.

Claims 10-13 and 20-22 may be amended to include either of the following statements at the end of each claim so they recite:

"... whereby the crystalline phase of Compound (I) is formed" or "... to form the crystalline phase of compound (I)".

This proposed amendment will clarify that the crystalline phase is formed at the conclusion (as a result) of the claimed steps.

Art Unit: 1654

Claims 12, 13, and 22 are product-by-process claims, and may be amended to recite:

"A crystalline phase of Compound (I) having at least a characteristic diffraction pattern peak at {insert appropriate value} degrees 2θ (± 0.4 degrees 2θ), prepared by a process comprising the following steps: ..."

This proposed amendment will distinguish over the prior art because the distinct diffraction pattern peak associated with the Compound (I) is neither anticipated nor suggested by the prior art.

Claims 24-26 are dependent upon Claims 12, 13, and 22 and do not require amendments *per se*.

Applicant may show evidence that the compounds prepared by the method in the prior art are not crystalline in morphology as instantly claimed to overcome the above art rejections.

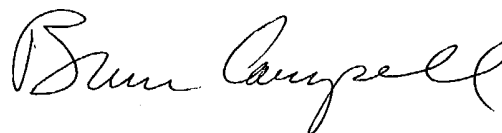
Alternatively, Applicant retains the right to cancel any claim(s) to overcome the above rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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